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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,117	08/06/2003	Daniel E. Couto	GTC-207	2070

31904 7590 11/28/2005

GTC BIOTHERAPEUTICS, INC.  
175 CROSSING BOULEVARD, SUITE 410  
FRAMINGHAM, MA 01702

EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/635,117		COUTO ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Robert B. Mondesi		1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6 and 10-72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 and 10-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2005 has been entered.

### ***Status of the claims***

**Claims 1-6 and 10-72** are presently pending and under examination.

### ***New Rejection(s)***

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 1-6 and 10-72** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have inserted the following limitation "greater than" in **claim 1 and 71**. As presently amended the claim states that the flux level is no longer maintained at a level ranging from about 5 to 100% of the transition flux but rather is now greater than 100% of transition point flux outside of the pressure dependent region. Even though the applicants have argued that this new limitation exists implicitly in the Data presented in the application, there is no direct factual bases for the "greater than" limitation. The Figure that the applicants have provided in the response section of the amendments filed June 20, 2005 and September 19, 2005 does not appear in any of the originally filed drawings and appears to have been created simply for the purposes of rebutting the prior rejection (The above New Matter issue is addressed below in the New Matter rejection paragraph). However, the examiner does see the point of the drawing and understands the applicants arguments but nonetheless presently stronger evidence in the form of Declarations is most likely required.

The amendment to **claim 6** including the limitation "or constitutes particles greater than 0.1  $\mu\text{m}$ " is also considered to be new matter since there is no direct support for the mentioned limitation in the present application.

**Claims 2-6 and 10-70 and 72** are included in this rejection because they are dependent claims that do not remedy the noted deficiencies.

**Claims 22, 70 and 71** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 1** limits to molecular species of proteins but **claim 22** adds RNA and DNA to these.

**Claim 71** recites the limitation "said permeate" in 6. There is insufficient antecedent basis for this limitation in the claim.

***Maintenance of rejection(s)***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

**Claims 1-7, 9-10, 14-19, 20-54, 59-61 and 71** are rejected under 35 U.S.C. 102(b) as being anticipated by van Reis et al. United States Patent 5,256,294.

This rejection was explained in the Office action mailed December 16, 2004.

***Claim Rejections - 35 USC § 103***

**Claims 12-13** are rejected under 35 U.S.C. 103(a) as being unpatentable over van Reis et al. United States Patent 5,256,294 in view of Kuni Hau et al.

This rejection was explained in the Office action mailed December 16, 2004.

***Response to Applicants' Arguments***

In regards to removal of the application from issue the applicants assert that the law does not allow for withdrawal of an application by the PTO after the issue fee has been paid.

In response the Examiner would like to point out that the application is withdrawn from issue after payment of the issue fee due to a mistake on the part of the Office.

According to rule CFR 1.313(b), applications may be withdrawn from issue for further action at the initiative of the Office.

The applicants assert that, it is important to point out that the original data remains the same from the filing of the specification. The chief differences with the prior art, and the apparent current difficulty is in the nature of the presentation of the data, not the data itself. The data show the optimal cross-flow rate, operating temperature, concentration factor, and the trans-membrane pressure (TMP) for the separation. Most importantly, the TMP was found to be optimal at approximately 15psig for the process described (Fig. 7), and as presented in the last response. This optimal psig would NECESSARILY entail a transition point pressure for flux. Unfortunately, when the data were presented in this manner it did not clearly demonstrate the differences in operating conditions between the ones used by Van Reis and GTC. This was because the inventors presented their data on a graph in one way and van Reis another.

More importantly the applicants have stated that they will provide such Declarations from the Inventors for the examples/data points presented.

Applicants' arguments with regards to the above are not found persuasive since no Declarations have been filed in the present application. Applicants have had ample time to file a Declaration had they desired to do so. Furthermore it must be pointed out that attorney arguments presented as fact are not a substitute for expert opinion or data (in particular since the applicants are arguing form over substance); therefore it is important that applicants' provide expert opinion in regards to the above matter. This is extremely crucial because the figure that the applicants have relied up on to base their

arguments from, "Diagram A" is not disclosed in the present application and only appears in the response section of amendment filed June 20, 2005 and September 19, 2005.

In regards to applicants assertions in view rejection of claims 35 U.S.C. 102(b) as being anticipated by van Reis et al., it must be pointed out that van Reis et al. teach transmembrane pressure at 15.7, 14.8, and 16.6 psi (Column 21, lines 12, 24 and 40) and that the flux may be held at a level greater than about 100% of transition point flux (column 13, line12 and line 28)

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

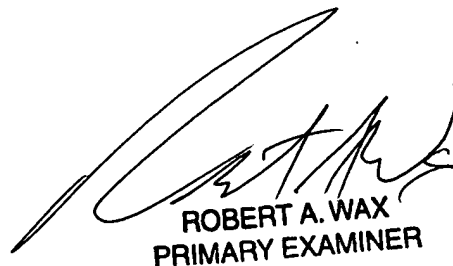
Art Unit: 1653

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi



11-21-05



ROBERT A. WAX  
PRIMARY EXAMINER